



## Getting Rid of Rotavirus

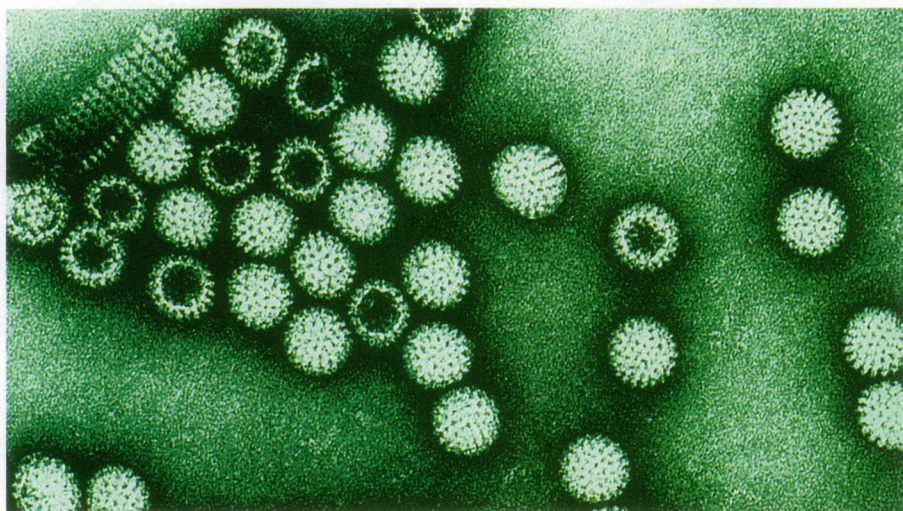
On 12 December 1997, the FDA's Vaccine and Related Biologicals Products Advisory Committee unanimously concluded that RotaShield, the first vaccine for rotavirus—a highly contagious disease that causes life-threatening diarrhea in young children—is safe and effective, and recommended licensing.

In the United States alone, rotavirus causes 3 million cases of childhood diarrhea, resulting in 500,000 doctor visits, 100,000 hospitalizations, and up to 100 deaths annually. Direct costs of the disease run to as much as \$400 million and indirect costs (such as lost work time for parents) total \$1.4 billion. Worldwide, rotavirus kills 873,000 children each year, largely in underdeveloped countries. The vaccine is intended to be administered in three doses at 2, 4, and 6 months of age when children receive their polio vaccine.

The RotaShield vaccine was created and patented by virologist and physician Albert Kapikian and his colleagues at the National Institute of Allergy and Infectious Diseases in Bethesda, Maryland. Kapikian, head of the epidemiology section of the Laboratory of Infectious Diseases, has devoted nearly 25 years to studying rotavirus. "It's exciting and gratifying as a physician to see that most babies can be protected from severe diarrhea with a product developed in our laboratory," he says.

Australian virologists discovered rotavirus in 1973. Later, several epidemiological studies proved that rotavirus was the most important agent involved in infantile diarrhea worldwide. Kapikian's ingenuity and perseverance helped overcome obstacles in creating the vaccine. For instance, human rotavirus resisted growth in cell cultures, whereas simian rotavirus grew well. The researchers worked to determine whether an animal rotavirus could protect humans, much in the same way that Edward Jenner determined 200 years ago that vaccinating people with cowpox could prevent smallpox. The final vaccine contains a weakened form of rotavirus obtained from rhesus monkeys, bioengineered with three genes from human rotavirus. This combination proved most effective at protecting people against the four most prevalent clinical strains of rotavirus.

The vaccine was tested successfully in numerous clinical trials. Among 2,000 infants in Venezuela, the vaccine reduced severe diarrheal illness by 88% and dehydration by 75%, and decreased hospitalizations



Charles Humphrey/CDC

**Last of a dying breed?** A new vaccine expected to be approved by the FDA may mean the end of rotavirus outbreaks.

by 70%. This study, reported in the 23 October 1997 issue of the *New England Journal of Medicine*, was the largest and most successful trial of the vaccine in a developing country. A multi-center trial conducted in the United States of 1,200 children showed that the vaccine protected 80% of the children against severe diarrhea and 100% against dehydration, as described in the January 1996 issue of *Pediatrics*. Another study, which appeared in the 25 October 1997 issue of *Lancet*, concluded that when tested on 2,400 Finnish children the vaccine reduced severe diarrhea by 91%, clinic visits for dehydration by 97%, and hospitalizations by 100%. In the latest study, published in the October 1997 issue of the *Journal of Pediatrics*, the vaccine prevented 69% of severe cases of diarrhea on American Indian reservations, where incidence rates of rotavirus disease run higher than for the general population. "The routine use of this vaccine could save lives and prevent illness," says Mathuram Santosham, director of the Johns Hopkins Center for American Indian and Alaskan Native Health in Baltimore, Maryland. In all clinical tests, the vaccine was safe and well-tolerated.

About 90% of all children are infected by rotavirus by age three regardless of hygienic conditions. Diarrhea is considered a normal part of childhood, and few hear about the small number of children who die yearly from rotavirus. Although a current television advertisement for a bathroom cleaner mentions that it kills rotavirus, in reality "parents in the U.S. don't know that rotavirus is a problem," says senior clinical

scientist Michael Pastorino of Wyeth-Ayerst Research in Radnor, Pennsylvania, a division of the company seeking licensure for the RotaShield vaccine. Both parents and physicians need to be educated about the new vaccine.

Wyeth-Ayerst is seeking a universal recommendation that all children be vaccinated for rotavirus from the Advisory Committee for Immunization Practices at the CDC, which sets the schedule of childhood immunizations.

## Stockpiling Safety?

By spring, the Nuclear Regulatory Commission (NRC) is expected to act, once again, on the 15-year-old issue of whether it makes sense for states to consider stockpiling thousands of tablets of potassium iodide (KI) near nuclear power plants in case of an emergency. No one disputes that KI, a benign substance long approved for over-the-counter use, is an effective thyroid-blocking agent. And no one is arguing that the cost of KI is prohibitive. A 130-mg tablet costs \$.07; supplying all residents within five miles of one of the United States' 107 operating nuclear reactors would cost as little as \$200,000 (although distributing and disposing of the supply would add costs). Few even question the safety of the tablets. The issue is whether having KI on hand would make some residents trust their fate to a pill rather than to evacuation.

Many states, as well as the nuclear industry, believe evacuation should be the first line of protective action in a nuclear emergency.